: 4160-90-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

# Supplemental Evidence and Data Request on Telehealth During COVID-19

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Request for Supplemental Evidence and Data Submissions.

**SUMMARY:** The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Telehealth During COVID-19,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

**DATES:** *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:**

*E-mail submissions:* epc@ahrq.hhs.gov

*Print submissions*:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

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Rockville, MD 20857

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**FOR FURTHER INFORMATION CONTACT:** Jenae Benns, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

**SUPPLEMENTARY INFORMATION:** The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Telehealth During COVID-19*. AHRQ is conducting this technical brief pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Telehealth During COVID-19*, including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/virtual-health-covid/protocol

This is to notify the public that the EPC Program would find the following information on *Telehealth During COVID-19* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
    - *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

*The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.*

**Key Questions (KQ)**

KQ 1. What are the characteristics of patient, provider, and health systems using telehealth during the COVID-19 era, specifically:

   a. What are the characteristics of patients (e.g., age, race/ethnicity, gender, socioeconomic status, education, geographic location (urban versus rural))?
   b. What are the provider and health system characteristics (e.g., specialty, geographic location, private practice, hospital-based practice)?
   c. How do the characteristics of patients, providers, and health systems differ between the first four months of the COVID-19 era versus the remainder of the COVID-19 era?

KQ 2. What are the benefits and harms of telehealth during the COVID-19 era?

   a. Does this vary by type of telehealth intervention (i.e., telephone, video visits)?
   b. Does this vary by patient characteristic (i.e., age, gender, race/ethnicity, type of clinical condition or health concern, geographic location)?
   c. Does this vary by provider and health system characteristic (e.g., specialty, geographic location, private practice, hospital-based practice)?

KQ 3. What is considered a successful telehealth intervention during the COVID-19 era:

   a. From the patient or caregiver perspective?
   b. From the provider perspective?

c. From the health system perspective?

KQ 4. What strategies have been used to implement telehealth interventions during the COVID-19 era?

a. What are the barriers and enablers of a successful telehealth strategy (e.g., setting, reimbursement, access to technology)?

- From the patient or caregiver perspective?
- From the provider perspective?
- From the health system perspective?

**Contextual Questions (CQ)**

CQ 1. What are the costs of implementation and return on investment for telehealth during the COVID-19 era to the provider/healthcare system?

CQ 2. What are the policy and reimbursement considerations for telehealth during the COVID-19 era?

a. How are these policy and reimbursement considerations for telehealth changing in the post-COVID-19 era (from March 2020, when the World Health Organization declared COVID-19 a pandemic to present); at the federal level (policies such as Medicare), state level (policies such as Medicaid), and by private insurance payers?

b. How do changes in reimbursement policies impact telehealth strategies?

**PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)**

**Table 1. PICOTS: Inclusion and exclusion criteria**

| PICOT | Inclusion | Exclusion |
|---|---|---|
| **Population** | All KQ:<br>• Patients of any age(or their caregivers for KQ3 KQ4)<br>• Health systems<br>• Hospitals<br>• Providers | All KQ:<br>Patients receiving inpatient care.<br>Providers providing inpatient care |
| **Interventions** | KQ 1-3:<br>• Remotely delivered synchronous medical services (e.g., telephone, video visits) between a patient and a healthcare provider in an | All KQ:<br>Remotely delivered, non-synchronous medical services (e.g., remote |

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| | ambulatory setting (e.g., outpatient and community-based clinics) or ED providing<br>○ acute/urgent care (e.g., symptom management); routine/chronic care (e.g., preventive services, chronic disease management); mental health services; wellness visits; post-hospital discharge care (e.g., routine follow-up and care for nonacute issues)<br>• Patient and specialist communications facilitated by an ED physician in an ED (particularly important in rural care setting)<br><br>KQ4: Implementation strategies for telehealth | monitoring devices, health apps, wearable devices, patient portals) |
| **Comparators** | KQ 1-3: In-person care, no care, no comparison<br>KQ 4: Implementation strategies for telehealth | NA |
| **Outcomes** | KQ 1: Not applicable<br>KQs 2 and 3:<br>○ Patient/provider-level outcomes<br>▪ Patient satisfaction/perceptions<br>▪ Physician /provider satisfaction/engagement/burnout<br>○ System outcomes<br>▪ Healthcare access (e.g., insurance coverage, WIFI and smartphone access)<br>▪ Healthcare utilization (e.g., hospitalization, readmission, ED visit)<br>▪ Healthcare performance and quality measures (e.g., adhering or meeting Healthcare Effectiveness Data and Information Set (HEDIS) standards or other validated quality measures), e.g.:<br>• Practice efficiency<br>• No-show rates<br>• Staffing hours<br>• Cycle times<br>▪ Communication<br>○ Clinical outcomes(any)<br>▪ Medication adherence<br>▪ Up to date lab values<br>○ Adverse effects/patient safety issues<br>▪ Inappropriate treatment<br>▪ Misdiagnosis/delayed diagnosis/care<br>▪ Case resolution/Duplication of services (telehealth followed immediately by in-person visit)<br>▪ Privacy/confidentiality breaches<br>○ Cost (see Appendix A for detailed cost outcomes)<br>KQ4:<br>○ Barriers and enablers | NA |
| **Timing** | All KQ: the era of COVID-19 (March 2020-present)<br>KQ1d: During the first 4 months or beyond the initial phase.* | Studies completed prior to the era of COVID-19 |
| **Setting** | ALL KQ:<br>○ Healthcare provided outside of a medical office via phone or video.<br><br>○ Healthcare provided in an ED by a specialist via phone or video.<br><br>○ U.S.-like outpatient population (including ED) (see Appendix B for a list of included countries) | Inpatient setting<br><br>Non-U.S. based studies with different patient population or health system characteristics. |

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| **Study Design**† | KQ1: claims and EHR data<br>KQ 2 and 4<br>o Qualitative studies: focus groups, interviews<br>o Quantitative studies: RCT, CT, observational studies, and surveys<br>KQ3: Qualitative studies: focus groups, interviews | |

* Studies that began before the era of COVID-19 (11 March 2020) and extend into the era of COVID-19 will be excluded unless they meet the following criteria: data from the pre and post COVID-19 era are stratified—the stratified data will be extracted; studies initiated as early as 1 January 2020 can be included if they are studies of telehealth in response to COVID-19.

† To be eligible for inclusion as a qualitative study, the Sampling, data collection, and data analyses must be systematically conducted; data must be analyzed using methods of qualitative data analysis (such as thematic analysis).

CT = controlled trial; ED = emergency department; EHR = electronic health record; HEDIS = Healthcare Effectiveness Data and Information Set; KQ = key question(s); NA = not applicable, RCT = randomized controlled trial

Dated: October 7, 2021.

**Marquita Cullom,**

*Associate Director.*

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